

## **II. Remarks**

### **A. Status of the Claims**

Claims 1, 3, 8-10, 12-27, 29-32, and 35-47 are currently pending.

### **B. Claim Rejection Under 35 U.S.C. § 103(a)**

Claims 1, 3, 8-10, 12-27, 29-32, and 35-47 were rejected under 35 U.S.C. § 103(a) over the combination of Nutt et al. (Clinical Pharmacology and Therapeutics, Vol. 15, Number 2, pp. 156-166), Mayer et al. (U.S. 5,556,838), Ockert (U.S. 5,376,662), European Patent No. 0 193 355, and Palermo et al. (US 6,627,635). The Examiner stated on page 2 of the Office Action that “Palermo et al. teach the use of an opioid agonist and an opioid antagonist for reducing the abuse potential of an oral dosage form,” and that “the combination of the claimed opioid agonist and antagonists, such as hydromorphone and naltrexone is taught in column 5, lines 14-20.” The Examiner did not state anything else about the Palermo patent.

The rejection is respectfully traversed, as the disclosure of the Palermo patent relied upon by the Examiner is not “prior art” to the present application.

The effective filing date for the disclosure of the use of an opioid agonist and an opioid antagonist for reducing the abuse potential of an oral dosage form and the disclosure of hydromorphone and naltrexone in the present application is December 22, 1997, the filing date of U.S. provisional application No. 60/068,489 to which the present application claims priority to. The ‘489 application describes the use of an opioid agonist and an opioid antagonist for reducing the abuse potential of an oral dosage form, e.g., in

the Abstract; hydromorphone, e.g., on page 14, lines 25-27; and naltrexone, e.g., on page 13, lines 26-30.

The Palermo patent was not filed before December 22, 1997, and does not claim priority to any applications filed before December 22, 1997. The Palermo patent was filed on March 22, 2001, and claims priority to U.S. provisional patent application No. 60/068,479, filed on December 22, 1997, through U.S. patent application No. 09/218,663, filed on December 22, 1998. Accordingly, Applicants submit that the Palermo patent cannot predate the December 22, 1997 effective filing date of the present application, and that the disclosure of the Palermo patent relied upon by the Examiner is not “prior art” to the present application.

Applicants therefore submit that the rejection is improper, as it relies on something that is not “prior art” to the present application.

Withdrawal of the rejection is respectfully requested.

## **B. Double Patenting**

Claims 1, 3, 8-10, 12-27, 29-32, and 35-47 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-27 of U.S. Patent No. 7,419,686 in view of European Patent Application No. 0 13 355.

Claims 1, 3, 8-10, 12-27, 29-32, and 35-47 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-21 of U.S. Patent No. 7,172,767 in view of European Patent Application No. 0 13 355.

Claims 1, 3, 8-10, 12-27, 29-32, and 35-47 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-29 and 59-63 of U.S. Patent No. 6,696,066 in view of European Patent Application No. 0 13 355.

Claims 1, 3, 8-10, 12-27, 29-32, and 35-47 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-23 of U.S. Patent No. 6,475,494 in view of European Patent Application No. 0 13 355.

Claims 1, 3, 8-10, 12-27, 29-32, and 35-47 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-25 and 50 of U.S. Patent No. 6,277,384 in view of European Patent Application No. 0 13 355.

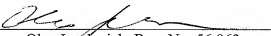
Claims 1, 3, 8-10, 12-27, 29-32, and 35-47 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-21 of U.S. Patent No. 6,375,957 in view of European Patent Application No. 0 13 355.

Applicants acknowledge these double patenting rejections, but respectfully request that the requirement to file terminal disclaimers to obviate these rejections be held in abeyance until such time as claims are otherwise held to be allowable.

**III. Conclusion**

An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,  
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